

# Regulatory Updates on Medical Devices in Korea



Ministry of Food and  
Drug Safety

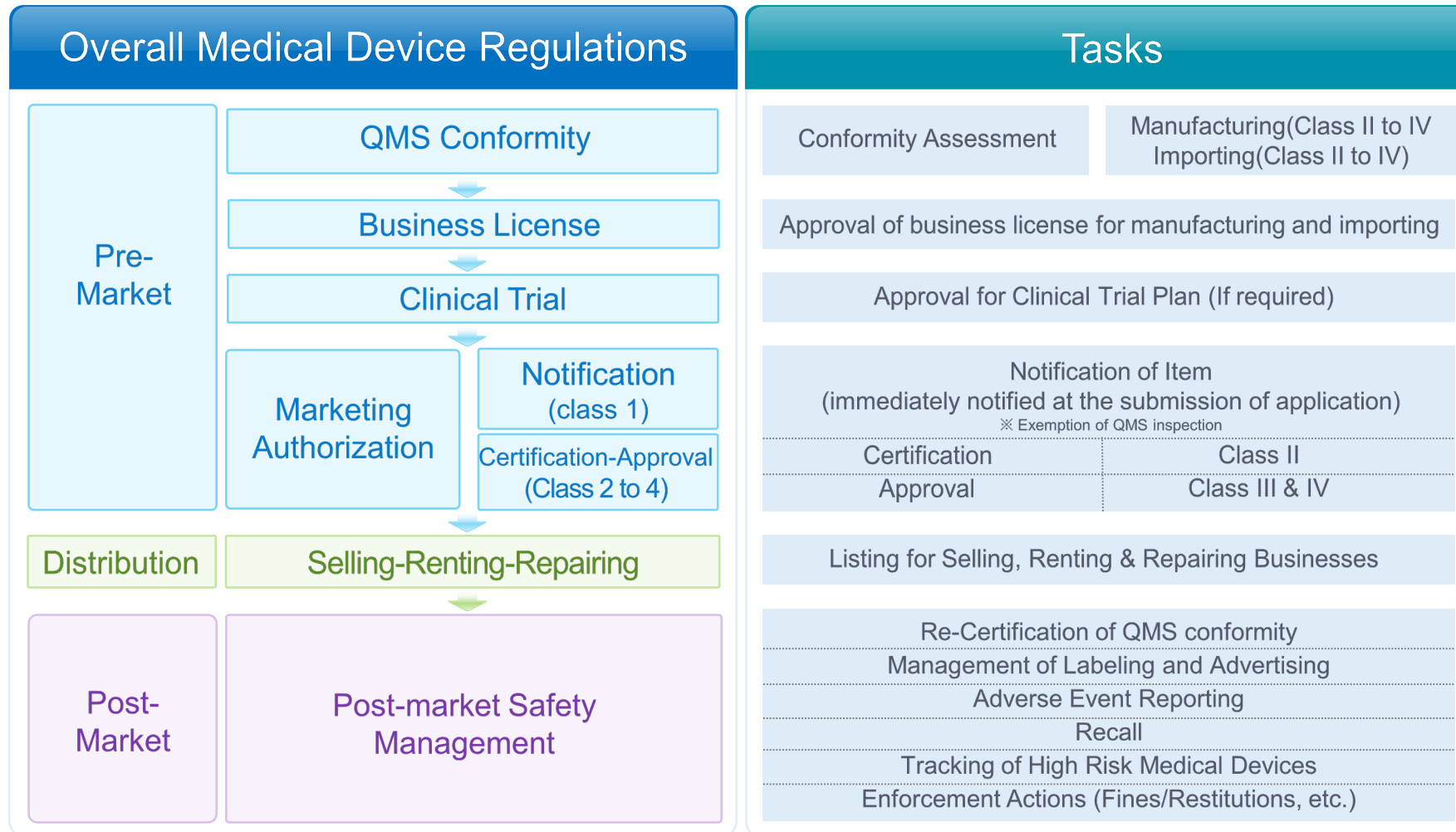
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# MFDS has an efficient and well-balanced system to manage the total lifecycle of medical devices





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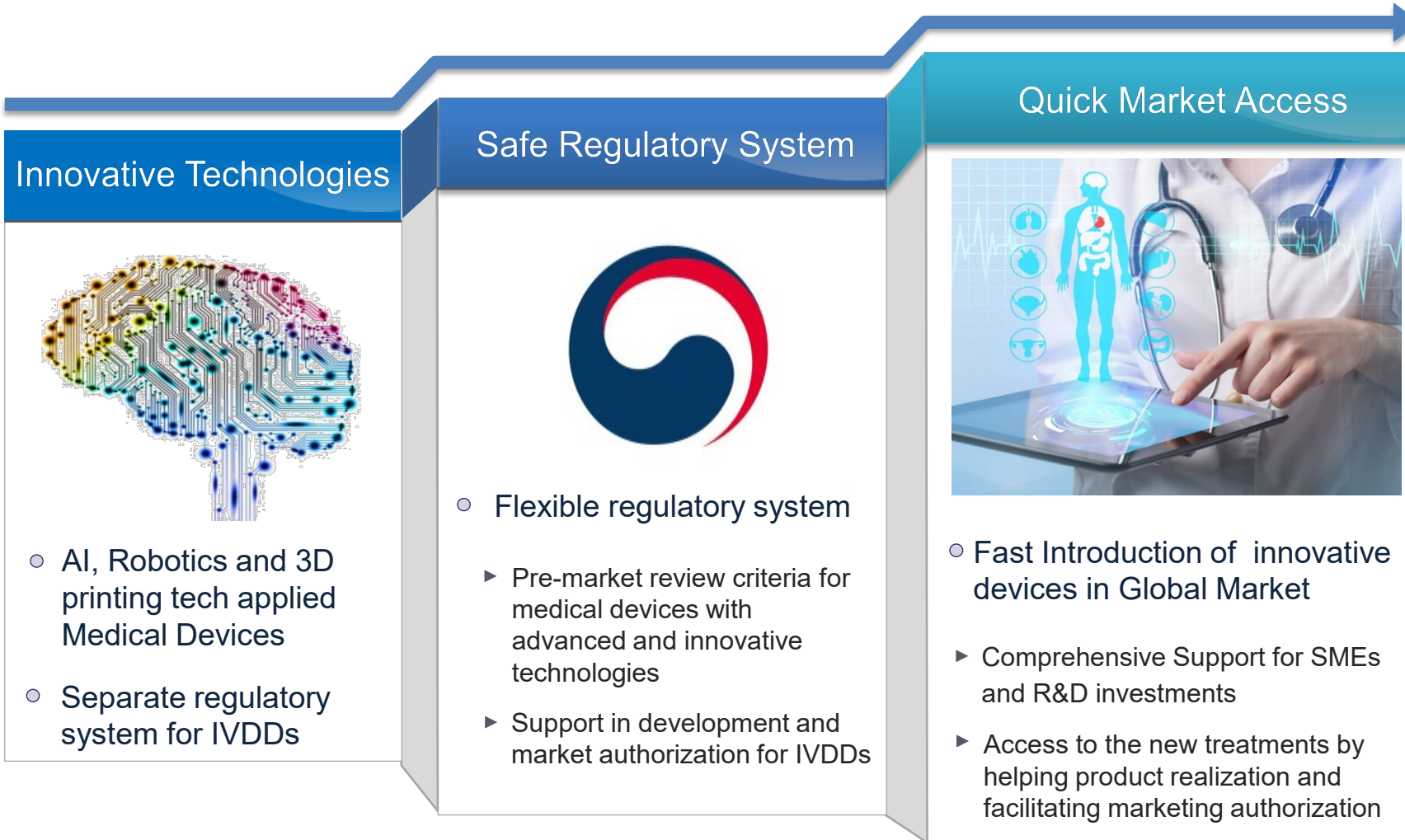
# 01

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## Act on Medical Device Industry Promotion and Innovative Medical Device Support

(legislated on April 30, 2019)  
(to be implemented by May 1, 2020)

# 1-1 Background of the Act



# 1-2 Act on Innovative Medical Devices

## 1. Certifying and Supporting Innovative Device Manufacturers

- **(Pre-certification Program)** application procedure and the requirements, **valid in 3 years**, rules for certification withdrawals
- **(Supporting the manufacturers)** preferential government-initiated R&D, tax exemption, a special exception for **constructing research facilities**

## 2. Designation and Supporting Innovative Device Groups

- **(Innovative devices groups)** valid in 3 years for the **recognized groups** for breakthrough improvement of the therapy and treatment for rare or intractable diseases
- **(Designating Innovative devices)** **designate innovative devices** that are applicable to the recognized group
- **(Supporting approval of Innovative devices)** **exempt business license, modular review process\* and priority review**
  - \* 4 phases : design & development, Safety & performance, Clinical trials and Technical docs & clinical data
- **(Post-market surveillance)** **less than 5-year period of follow up surveillance** required when needed a follow up for its clinical efficacy and adverse events observation

### 3. Special Exception for Innovative Software Devices

- **(Pre-certification program)** exemption of some submission requirements for the **pre-certified software manufacturers** by appraising the organization and personnel
- **(Modification approval)** amendment approvals required for major changes and report for other changes
- **(Clinical trial)** clinical trials for innovative software medical devices with **IRB approvals**
- **(GMP/QMS)** Good Management Practice established for software medical devices

### 4. Support for the Technology

- **(R&D)** R&D initiatives, necessary information sharing, establishing basis for rewarding outstanding developers
- **(Clinical investigations)** support for clinical researches and clinical trials for conducting such investigations by MFDS and MOHW
- **(Safe regulatory framework)** support for studies and tests to acquire its safety and effectiveness, and manufacturing & quality management system

# 02

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## Act on In-Vitro Diagnostic Devices

(legislated on April 30, 2019)  
(to be implemented by May 1, 2020)



## 2-1 Background and the Needs for an Act on IVDDs

### Background

- Specific Support for IVD Device development and product realization
- Promotion of modernization of regulations

### Needs

- To provide verification for accuracy of diagnosing diseases using specimen
  - ✕ need to have the IVD-specific review procedures
- To have an individual management system for IVD devices
  - ✕ Internationally harmonized and Standardized framework

## 2-2 Act on In-vitro Diagnostic Medical Devices

### Definition of IVD devices

"In-vitro diagnostic medical devices" shall mean reagents used ex vivo for the purpose of providing information on, such as diagnosis of diseases, observation of prognosis and determination of tissue or blood compatibility, using human-derived samples as specimen. Provided, reagents mixed at laboratories shall be excluded.



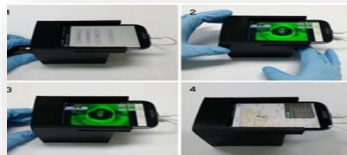
<NGS system>



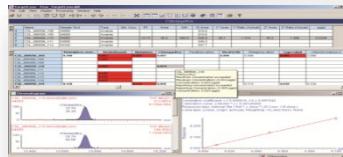
<Diagnostic reagent for genetic diseases>



<Smart Contact Lens by INTEROJO>



<Portable to measure fluorescence -  
diagnosing infectious diseases>



<Various software for diseases testing>



<Pregnancy testing devices>

## 2-3 Act on In-Vitro Diagnostic Medical Devices

### Classifications of IVDDs

- Classifying and designating IVD devices based on the purpose of use and potential risks for the public health in accordance with characteristics of the IVD devices

### Simultaneous Approval of IVD CDx devices

- Simultaneous approval for IVD CDx devices and drugs that are used with the device

### Modification Approval

- Negative approach for modifications
  - ▶ amendment approvals for major changes with an impact on safety and effectiveness
  - ▶ amendment reports for any other changes



03

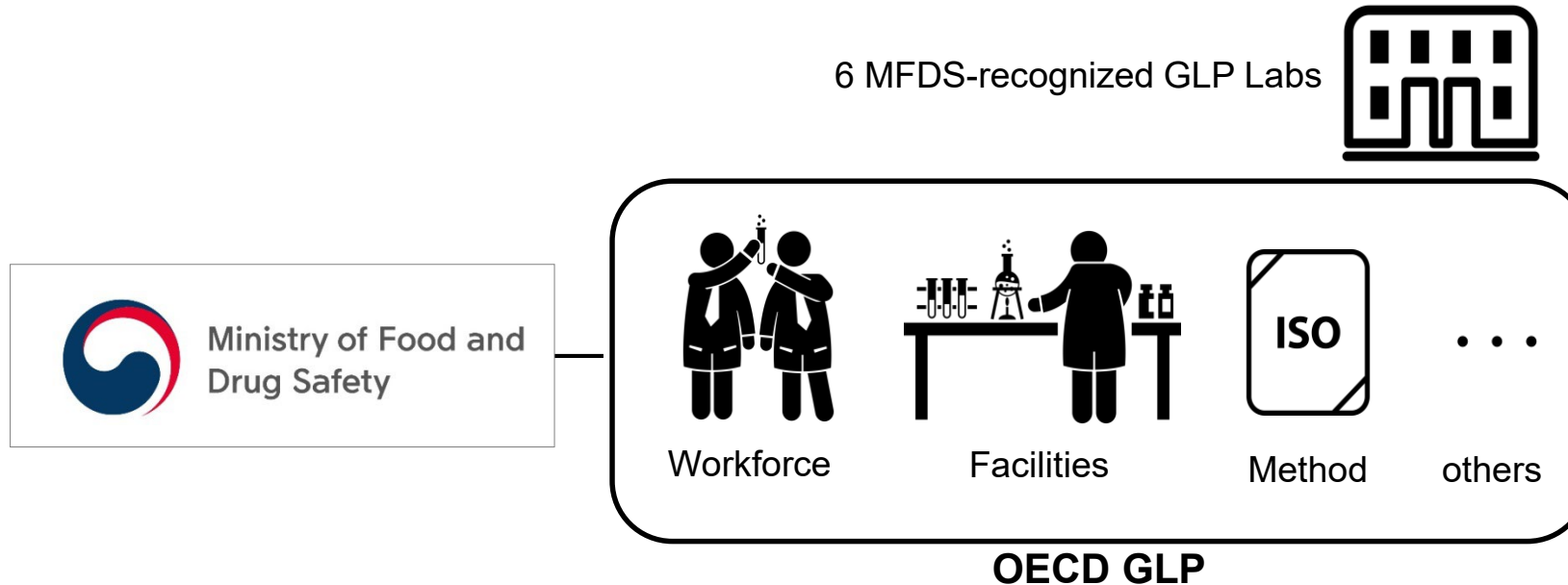
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## UDI System and GLP for Medical Devices

## UDI System Implementation in Korea

|             | Class 4<br>(high risk) | Class 3<br>(serious risk) | Class 2<br>(potential risk) | Class 1<br>(lower risk) |
|-------------|------------------------|---------------------------|-----------------------------|-------------------------|
| Placing UDI | <b>July, 2019</b>      | July, 2020                | July, 2021                  | July, 2022              |

## Implementation of GLP for Medical Devices (since May 1, 2019)





04

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## Agreements with Academia

# Agreement between MFDS-Academia leading to robust systematic review



Ministry of Food and  
Drug Safety



The Korean Society of  
Medical & Biological Engineering



The Korean Society  
of Medical Informatics



The Korean Society  
for Biomaterials



대한의료인공지능학회  
Korean Society of Artificial Intelligence in Medicine

A modern, multi-story building with large windows and a curved facade is visible in the background. A semi-transparent teal rectangle is overlaid on the image, containing the text. The number '05' is prominently displayed in white, bold font, with a thin white horizontal line underneath it.

# 05

New Guidelines  
(since April 1, 2019)

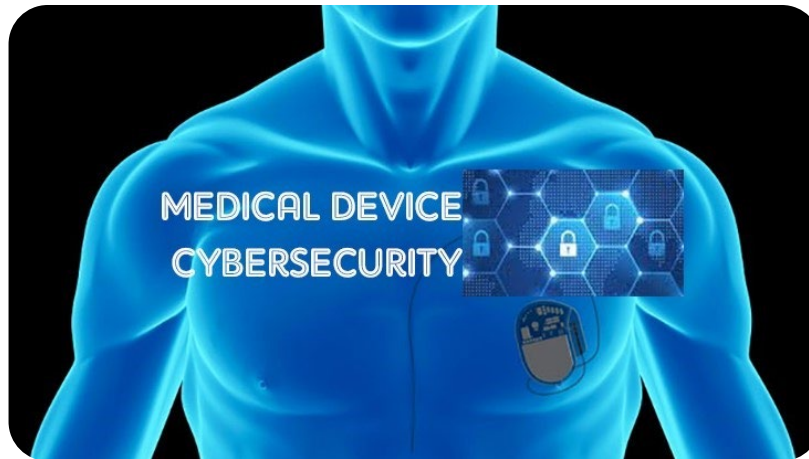


## Cybersecurity-related Guidelines (Draft)

### Medical Device Cybersecurity Guideline

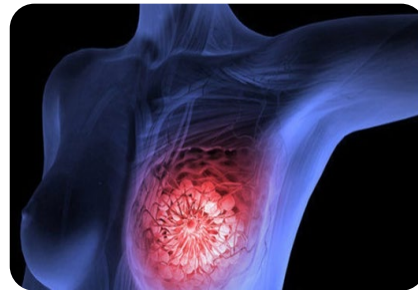


- **A draft guideline on pre-market review and approval for medical device cybersecurity (Jan, 2019)**
  - Contents : the applicable scope, definitions and classification for safety, 24 requirements for security and submissions documents required
- **A draft guideline on how to apply cybersecurity on medical devices and practical cases (Jan, 2019)**



## Guideline on Clinical Trial Protocols of AI-based Medical Devices (Draft)

- **A protocol development guideline for retrospective clinical trials** on AI-based software medical devices classified by four (4) diseases of **breast cancer, lung diseases, coronary stenosis and cerebral ischemic stroke**
  - **Guideline of criteria to select or exclude sample data, monitoring regime, how to conduct clinical trials and standards for effectiveness evaluation criteria according to the respective characteristics**



## Newly developed guidelines

July, 2019

[New] Guideline on 3D printed personalized medical devices according to manufacturing process  
- (7 types) modeling, process, material, post-treatment and cleaning, conformity, identification and traceability

May, 2019

[New] Guideline on comprehensive operation of evaluation on new medical technologies for approvals as a medical device  
- Including review and approval by MFDS, whether to be covered, simultaneous review for evaluation of new medical technologies

April, 2019

[New] Guideline and FAQ on GCP for medical devices  
- FAQ on applying Good Clinical Practice on medical devices

## Newly developed guidelines

April, 2019

- [New] Guideline for business license holders on reporting recalls
- Reporting procedures and how to report recalls

April, 2019

- [New] Guideline for regional offices on addressing recalls by business license holders
- Review procedures and the standards to address recalls done by the business license holders

## Revised guidelines

July, 2019

[Revision] Guideline on In-vitro diagnostic medical devices  
- Including major changes of IVD devices and examples of submission documents

July, 2019

[Revision] Guideline on amendment approval for In-vitro diagnostic medical devices  
- Including practical cases of technical documents (changes) or minor changes

July, 2019

[Revision] Guideline on performance evaluation of NGS IVD medical devices  
- including review process of reagents for genetic testing related to tumor using NGS

July, 2019

[Revision] Guideline on detailed GMP Inspection for imported medical devices manufacturers  
- Revised in alignment with the revision of Medical Device GMP in Korea

April, 2019

[Revision] Guideline on addressing recalls by the government  
- Reflected modifications of Medical Device Act Enforcement Regulation

The background of the slide is a photograph of a modern, multi-story building with large windows and a curved facade. A semi-transparent teal rectangle is overlaid on the center of the image, containing the text. The overall lighting is somewhat dim, suggesting an overcast day or early morning/late afternoon.

# 06

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## Policy Strategy

# 6 Policy Strategy

## 1. Regulatory Framework for Innovation

- Subordinate legislation in line with the Acts
  - ▶ The enforcement decree and the enforcement regulation for the detailed regulatory contents followed by the Acts

## 2. Total Lifecycle Management

- To report medical device supply information to help get through the information on manufacture, distribution and use
  - ▶ Revision on medical device act enforcement regulation (July, 2019) and legislation on the details

## 3. Solution for Regulatory Blind Spots

- Expanding of designations through humanitarian device program
  - ▶ real time monitoring and responding to the insufficient products



Thank you